DIN EN ISO 80601-2-90:2022-03 (E)

Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment (ISO 80601-2-90:2021)

Contents

Page

European foreword 4

Foreword 5

Introduction 6

201. 1 Scope, object and related standards 8

201. 2 Normative references 11

201. 3 Terms and definitions 12

201. 4 General requirements 17

201. 5 General requirements for testing of *ME equipment* 19

201. 6 Classification of *ME equipment* and *ME systems* 20

201. 7 *ME equipment* identification, *marking* and documents 20

201. 8 Protection against electrical *hazards* from *ME equipment* 27

201. 9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 27

201. 10 Protection against unwanted and excessive radiation *hazards* 28

201. 11 Protection against excessive temperatures and other *hazards* 29

201. 12 Accuracy of controls and instruments and protection against hazardous outputs 33

201. 13 *Hazardous situations* and fault conditions for *ME equipment* 40

201. 14 *Programmable electrical medical systems* (*PEMS*) 41

201. 15 Construction of *ME equipment* 41

201. 16 *ME systems* 42

201. 17 Electromagnetic compatibility of *ME equipment* and *ME systems* 43

201.101 Gas connections 43

201.102 Requirements for the *breathing system* and *accessories* 46

201.103 * Indication of duration of operation 47

201.104 *Functional connection* 48

201.105 *Power supply cords* 48

201.106 *Respiratory high-flow therapy equipment* security 49

202 Electromagnetic disturbances — Requirements and tests 49

206 Usability 50

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems 51

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment 53

Annex C (informative) **Guide to *marking* and labelling requirements for *ME equipment* and *ME systems*** **55**
Annex D (informative) ***Symbols* on *marking*** **61**
Annex AA (informative) **Particular guidance and rationale** **62**
AA.1 General guidance **62**
AA.2 Rationale for particular clauses and subclauses **62**
Annex BB (informative) **Data interface requirements** **76**
BB.1 Background and purpose **76**
BB.2 Data definition **77**
Annex CC (informative) **Reference to the IMDRF *essential principles* and labelling guidances** **80**
Annex DD (informative) **Reference to the *essential principles*** **83**
Annex EE (informative) **Reference to the general safety and performance requirements** **86**
Annex FF (informative) **Terminology — Alphabetized index of defined terms** **89**
Bibliography **93**